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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416

7590 01/30/2002

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EXAMINER	
DO, PENSEE T	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/599,870	BRENNAN ET AL.	
	Examin r	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *14-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-13 in Paper No. 3 is acknowledged. The traversal is on the ground(s) that the remaining groups of claims should be rejoined upon allowance of the elected claims, under the Ochiai guidelines, provided that they comply with the criteria for rejoinder. In the event that the claims of the elected product of group I is allowable, the method of making the product and the method of using the product would be reconsidered according to the Ochiai guidelines.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is a duplicate of claim 1. Please cancel either one and renumber the claims.

Claim 5, "the material" lacks antecedent support. If it refers to the inorganic, organic material, please clarify and be consistent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne et al. (WO 9603117A1).

Ducheyne teaches carriers comprising silica-based glass providing for the controlled release of biological active molecules. The carriers are prepared by using sol-gel-derived method. Biologically active molecules are incorporated within the matrix of the glass during production. The carrier comprises of material such as silicon-based metal alkoxide. (see page 11, lines 5-10). The carrier having biologically active molecules incorporated within the matrix of the glass is pre-treated by immersion in a solution containing ions typical for interstitial fluid for a period of up to seven days prior to use. (see page 12, lines 28-33). The carriers are synthesized under sterile conditions or can be sterilized using conventional sterilization method. (see page 15, lines 1-2).

Claims 6 and 9-12 are not given any patentable weight because these are process claims. Regardless of how the product of the present invention is made, if such

product has the same components of that of the prior arts, then these prior arts meet the requirement of the invention.

Claims 1, 3-5, 7, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Latorre et al. (WO99/07777).

Latorre teaches a composition including a glass composition and a biodegradable polymer. The glass is formed from oxides of silicon, phosphorus, sodium and calcium and is dispersed within a porous biodegradable polymer to form a three dimensional matrix. The composition also includes biologically active substances such as those which promote healing and regulate cell/tissue growth, including bone growth. Such substances include growth factors, antivirals, antibacterials, antiinflammatories, immunosuppressants, analgestics, proteins, etc. (see page. 9, 3rd paragraph; abstract).

Claims 1, 3, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Sankaram (US 6,277,413B1).

Sankaram teaches a biodegradable composition for the controlled release of encapsulated substances. The composition is provided by encapsulation of physiological active substances into the matrix comprising a biodegradable polymer and lipids. The rate of release is controlled by varying the ratio of the polymer to the lipid. The physiologically active substances include small molecules, peptides, proteins, nucleic acids and vaccines. The biodegradable polymers include homopolymers, random or block copolymers. (see abstract; col. 2, line 43- col. 3, line 56).

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Staas et al. (US 6,312,731).

Staas teaches a composition for inducing an immune response in a subject, comprising antigen and/or a non-antigen bioactive agent capable of inducing such an immune response encapsulated by a polymeric composition, wherein the polymeric composition comprises a blend of a polymer present an amount sufficient to provide structural integrity to the polymeric composition and a rapidly biodegradable component, a rapidly dissolving component, a rapidly swelling component and a component that causes osmotic rupture of the encapsulated polymeric composition. (see col. 2, line 40-col. 8, line 40).

Claims 1, 3, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Guillen (US 6,074,673).

Guillen teaches a controlled release delivery system including a functional gene vector and a biodegradable polymer microsphere encapsulated the vector. The gene vector is selected from the group consisting of viruses, bacteriophage, plasmids and purified DNA fragments. (see col. 5, line 51-col. 6, line 65).

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Hagan et al. (US 5,603,960).

O'Hagan teaches a pharmaceutical composition comprising a polymer containing an aqueous solution of the bioactive material to be encapsulated (e.g. an aqueous solution of antigen). The bioactive materials include agricultural agents such as insecticides, fungicides, herbicides, hormones, steroids, enzymes, protein or peptides, substances that induce an immunogenic response in general, etc. (see col. 4, lines 10-60).

Claims 1, 3, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein et al. (US 5,679,377).

Bernstein teaches biodegradable protein microspheres which are used for in vivo release of a biologically active agent. A variety of materials that can be incorporated into the microspheres, include biologically active agents such as proteins, organic compounds, etc. The microspheres can be administered enterally, topically (to the skin, eyes, and orifices), or subcutaneously for subsequent release. (see col. 2, lines 30-50).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jou et al. (US 5,866,322).

Jou teaches a solid phase comprising of a porous fibrous matrix material coated with a polymeric quaternary ammonium compound. The solid phase is also coated with a capture reagent, for example an antibody, for the analyte to be assayed. (see abstract; col. 6, lines 30-50).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
January 26, 2002

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641